

DEC 26 2001



**FLORIDA OPTICAL ENGINEERING, Inc.**

510(k) Premarket Notification

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**510(k) PREMARKET NOTIFICATION**

**Summary of Safety and Effectiveness**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

**The Assigned 510(k) Number:**      **K013445**

**Applicant Information**

Date Prepared:                      September 22, 2000  
Name:                                  Florida Optical Engineering, Inc.(FLOE)  
Registration Number:                \_\_\_\_\_  
Address:                                13709 Progress Boulevard, Box 14  
   Alachua, Florida 32615  
Contact Person:                      Richard A. Griffin, O.D., President  
    Phone Number:                    (386) 418-4397  
    Fax Number:                        (386) 418-4397  
    e-mail Address:                    drrichardagriffin@alltel.net

**Manufacturing and Sterilization**

   Euclid Systems Corporation  
   2810 Towerview Road  
   Herndon, VA 2017  
  
Contact Person:                      George E. Glady, VP Operations  
    Phone Number:                    800-447-9396  
    E-mail Address:                    George@Euclid.sys

**Device Information**

Device Classification:              Class II  
Classification Number:              LPL  
Classification Name:                Soft Contact Lenses, Daily Wear  
Trade/Proprietary Name:          OSPREY™ Spherical (hioxifilcon B) Multifocal  
   Soft Daily Wear Contact Lenses  
   and  
   OSPREY™ Toric (hioxifilcon B) Multifocal Soft  
   Daily Wear Contact Lenses



## **FLORIDA OPTICAL ENGINEERING**

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The material, Benz-G 5X (hioxifilcon A), may be disinfected using a chemical (non-thermal) disinfection system.

3. UltraVue/P and UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lenses (Clear and Blue Visibility Tint, Lathe-cut from Lens Blanks) is the predicate device because it is manufactured from:
- (a) the same polymer (hioxifilcon B), the polymer which already has FDA clearance,
  - (b) using similar multifocal lens designs and
  - (c) using lathe-cutting equipment.

UltraVue/P and UltraVue/C (hioxifilcon B) soft contact lenses made from clear and a blue visibility tint BENZ-G 3X lens blanks are intended for daily wear for correction of visual acuity of aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The Lenses may be worn by people who may exhibit astigmatism of 0.75 Diopters or less where astigmatism does not interfere with visual acuity.

The material, Benz-G 3X (hioxifilcon B), is non-ionic polymer that may be disinfected using either the heat (thermal) or chemical (non-thermal) disinfection system.

The physical properties of the lens blanks made from Benz-G 3X (hioxifilcon B) lens polymer material, which are used to manufacture predicate devices number 1 and 3 are listed in Table 4.

**Table 4. Physicochemical Properties(\*) of Benz-G 3X (hioxifilcon B) Lens Blanks Polymer Material.**

<b>Refractive Index</b>	1.515 (dry) and 1.425 (hydrated)
<b>Color Pigment Name</b>	Phthalocyanine Blue
<b>Light Transmission (Clear)</b>	greater then 95% T
<b>Light Transmission (Tinted)</b>	greater then 95% T
<b>Water Content</b>	48% by weight
<b>Specific Gravity</b>	1.308 (dry) and 1.136 (hydrated)
<b>Oxygen Permeability</b>	15 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec)(ml O <sub>2</sub> /ml x mm Hg@35°C)

(revised Fatt Method)

(\*) NOTE: Data Taken from Technical Manual, Benz Research and Development, Inc. (April 1999)



## INTENDED USE

The **OSPREY Spherical (hioxifilcon B) Multifocal Soft Contact Lenses** are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia. The lenses may be worn by persons with astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The **OSPREY Toric (hioxifilcon B) Multifocal Soft Contact Lenses** are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia and astigmatism of 4.5 diopters or less.

Eye care practitioners may prescribe the lenses for planned replacement wear with cleaning, disinfection and scheduled replacement (See WEARING SCHEDULE). When prescribed for planned replacement wear, the lenses may be disinfected using either a heat or chemical disinfection system.

## DESCRIPTION OF DEVICE

**OSPREY™ Spherical or Toric (hioxifilcon B) Multifocal Soft Daily Wear Contact Lenses (Clear and Blue Visibility Tint, Lathe-cut from Lens Blanks)** are made from clear and a blue visibility tint BENZ-G 3X (hioxifilcon B) lens blanks intended for daily wear for correction of visual acuity of aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lenses are manufactured by lathe-cutting of lens blanks in dry (i.e. non-hydrated) state into hemispherical shell which can be polished when desired. The toric contact lens have a Toric Base Curve.

**Osprey™ Multifocal Soft Contact Lens** is a center-distance, simultaneous-focus, progressive-addition lens. Focal power within the central power zone is generated on the front surface, beginning at the central distance power, and increasing radially outward. Labeled Add Power is that Add Power which is occurring at the pupillary zone diameter of 3.5 mm. The back surface may be either spherical or toric for correcting astigmatism. The toric lens is held on axis by the superior and inferior front surface flanges, formed by slab-off. The lenses are available in clear and with a blue visibility tint as supplied by the manufacturer of lens blanks.

Side-by-side comparison of the key physical/chemical/optical properties of the **Osprey™ Multifocal** Contact Lens compared with the lenses to which substantial equivalence is sought is given in Table 5. As can be seen from this table, the Present Device, that is, **OSPREY™ Multifocal Soft Contact Lens** satisfies the requirements for substantial equivalency determination. Only difference is in the shape of lens curvature, which defines the optics, all other aspects are the same for this lens and predicate devices.



DEC 26 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Richard Griffin, O.D.  
Florida Optical Engineering, Inc. (FLOE)  
13709 Progress Boulevard, Box 14  
Alachua, FL 32615

Re: K013445

Trade/Device Name: Osprey (hioxifilcon B) Spherical and Toric Multifocal Lens  
for Daily Wear.

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft Contact Lens, Daily Wear

Regulatory Class: Class II

Product Code: LPL

Dated: October 17, 2001

Received: October 17, 2001

Dear Dr. Griffin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, reading "A. Ralph Rosenthal". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health



**FLORIDA OPTICAL ENGINEERING, Inc.**

510(k) Premarket Notification

**INDICATIONS FOR USE STATEMENT**

**510(k) Number:** K013445

**Device Name:** OSPREY™ Spherical or Toric (hioxifilcon B) Multifocal Soft Daily Wear Contact Lenses (Clear and Blue Visibility Tint, Lathe-cut from Lens Blanks).

**Indications for Use:**

The OSPREY Spherical (hioxifilcon B) Multifocal Soft Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia. The lenses may be worn by persons with astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The OSPREY Toric (hioxifilcon B) Multifocal Soft Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with presbyopia and astigmatism of 4.5 diopters or less.

  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K013445

Prescription Use X  
(Per 21 CFR 801.109)